

### **REMARKS**

Prior to the entry of this Amendment, claims 19-36 were pending in this application. Claims 19, 23-25 and 28-29 have been examined on their merits, and stand rejected. Claims 21, 22, 24-27 and 30-36 have been withdrawn by the Examiner as directed to non-elected subject matter. Applicants expressly reserve the right to file one or more continuation or divisional application(s) directed to the non-elected subject matter that is not rejoined with this application. Specifically, the claims stand rejected as anticipated and/or obvious in view of the cited references.

Applicants have amended claim 19, and have added new claims 37-39. Support for the amendment to claim 19 can be found in the specification, for example, at page 6, lines 3-5. Support for new claims 37-39 can be found in the specification, for example, at page 7, lines 27-28; page 8, line 15-18; and page 8, lines 30-33. Thus, no new matter has been added.

### **REJECTION UNDER 35 U.S.C. § 102**

Claims 19 and 28-29 have been rejected under 35 U.S.C. § 102(b) as anticipated by Masor.<sup>1</sup>

Claim 19 has been amended to recite that the trauma is selected from the group consisting of surgery, burns, lesions and hemorrhage. Masor is directed to enhancing the immune system of a human via infant formulae.<sup>2</sup> The Examiner contends that diarrhea is a form of trauma. Since claim 19 has been amended to exclude diarrhea, Masor does not teach each and every element of this claim. Also, since claims 28 and 29 depend from claim 19 and therefore contain all of the limitations recited in claim 19, as amended, Masor does not teach each and every element recited in these claims. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

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<sup>1</sup> United States Patent Number 5,602,109 to Masor *et al.* ("Masor").

<sup>2</sup> Masor at abstract.

### REJECTION UNDER 35 U.S.C. § 103

Claims 19, 23-25, 28 and 29 stand rejected under 35 U.S.C. § 103(a) as obvious over Alexander<sup>3</sup>.

Claim 19 is directed to a method of reducing the risk of developing multiple organ dysfunction (e.g. organ failure) in a mammal. In contrast, Alexander is directed to stimulating or re-stimulating the immune system where the immune system was compromised after trauma. Thus, the recited multiple organ dysfunction is different from the condition being treated in Alexander. Since Alexander does not teach or suggest inducing the risk of multiple organ dysfunction, claim 18 and the claims depending therefrom, are patentable over Alexander.

Furthermore, Alexander states that its immunostimulatory compositions comprise a compound associated with the synthesis of polyamines, a nucleobase source, an omega-3 polyunsaturated fatty acid, and an omega-6 polyunsaturated fatty acid.<sup>4</sup> It states that the nucleobase could be one of at least 23 different nucleobases, one of them being guanosine. In fact, Compound A, which the Examiner specifically cites, does not contain guanosine. Instead, it contains a mixture of the following nucleobases: uracil, cytosine, guanine, adenine and thymine.<sup>5</sup> And while Compound A contains a “carbohydrate source”, namely maltodextrins, Alexander only mentions that a carbohydrate source may be used without providing a specific motivation to combine the recited digestible water soluble with guanosine.

A combination of known elements will not yield predictable results if the references disclose a broad selection of compounds or combinations, or if the references teach away from the claimed invention. See *Takeda Chemical*, 492 F.3d at 1359; also see *Ortho-McNeil Pharmaceutical, Inc. v. Mylan*, 520 F.3d 1358, 1364 (Fed. Cir. 2008); and also see *Ex parte Ikeda*, App. No. 08/352,079, Appeal 2008-0492, Slip Op. at 7 (BPAI Mar. 26, 2008). Here, there is no teaching or suggestion to combine guanosine and a digestible water soluble carbohydrate because there is no reason to pick-over the over 23 different nucleobases to just use

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<sup>3</sup> United States Patent No. 5,231,085 to Alexander *et al.* (Alexander).

<sup>4</sup> Alexander at column 2, lines 19-26.

<sup>5</sup> Alexander at column 6, lines 23-27.

guanosine, or to add a carbohydrate that is digestible and water soluble. Furthermore, there is no reason provided why one would have expected such a combination to be useful in the recited method – to reduce the risk of developing multiple organ dysfunction.

In addition to the above, claim 25 is separately patentable over Alexander. Claim 25, which depends from claim 23, further recites that “the liquid composition is administered within 24 hours prior to the occurrence of the surgery.” In contrast, Alexander teaches administering its compound at 11:00 am on the first postoperative day, which is greater than 24 hours prior to the occurrence of surgery because the first postoperative day is approximately 24 hours after surgery. Thus, for this additional reason, claim 25 is patentable over Alexander.

In addition to the reasons stated above with regard to claim 19, Applicants believe that new claims 37-39 are separately patentable over Alexander because Alexander does not suggest the importance of folic acid, and does not teach or suggest AEDC-inhibiting peptides or flavonoids.

### **REQUEST FOR REJOINDER**

Applicants respectfully request that claims 20, and 24-27, which are drawn to non-elected species, be examined and allowed because claim 19 is a generic claim that encompasses that species recited in claims 20 and 24-27, and because claim 19 is in condition for allowance.<sup>6</sup> The Applicants further request that the non-elected claims 30-36 be rejoined.<sup>7</sup>

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<sup>6</sup> See MPEP § 809.02(a).

<sup>7</sup> See MPEP § 821.04.

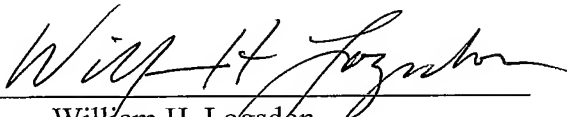
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### CONCLUSION

In view of these amendments and remarks, Applicants respectfully request that the objections and rejections be reconsidered and withdrawn, that claims 19, 21-23, 28-29 and 37-39 be allowed, and that claims 20, 24-27 and 30-36 be rejoined.

Respectfully submitted,

THE WEBB LAW FIRM

By 

William H. Logsdon  
Registration No. 22,132  
Attorney for Applicants  
436 Seventh Avenue  
700 Koppers Building  
Pittsburgh, PA 15219  
Telephone: (412) 471-8815  
Facsimile: (412) 471-4094  
E-mail: [webblaw@webblaw.com](mailto:webblaw@webblaw.com)